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REPORT
No. 98–32

SACCHARIN STUDY AND LABELING ACT AMENDMENTS OF 1983

MARCH 23 (legislative day, MARCH 21), 1983.—Ordered to be printed

Mr. HATCH, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 89]

The Committee on Labor and Human Resources, to which was referred the bill (S. 89) to amend the Saccharin Study and Labeling Act, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

I. SUMMARY OF LEGISLATION

S. 89 further amends section 3 of the Saccharin Study and Labeling Act (Public Law 95–203, as amended by Public Law 96–273 and Public Law 97–42 to extend to "twenty-four months after the date of enactment" of this act, the prohibitions on actions by the Secretary of Health and Human Services respecting saccharin.

II. HISTORY OF S. 89 INCLUDING HEARINGS

S. 89 was introduced on January 26, 1983, by Senator Orrin G. Hatch, and was referred to the Committee on Labor and Human Resources. Because the existing statutory deadline will expire early in this Congress, and because of the lack of controversy surrounding a further 2-year extension, the committee voted without objection to report S. 89 without benefit of further hearings. The vote was 17 to 0, with one member not voting.

III. BACKGROUND AND COMMITTEE VIEWS

This committee last filed a report on the issue of saccharin less than two years ago. (Senate Report 97–140, June 19, 1981). And just a year

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earlier, this committee had filed a report, (Senate Report 96–715, May 15, 1980), detailing the history of the use of saccharin and studies conducted on its safety. Since then, two large-scale animal studies of the safety of saccharin have been undertaken, one by the National Center for Toxicological Research, and the other by the International Research and Development Corporation. These studies were intended to address numerous questions raised in previous studies. Their results should be available for analysis, by the scientific community and this committee, later this year. Furthermore, although development of substitutes continues, no substitute for all uses of saccharin is likely to be available commercially during the extension provided for in S. 89.

The committee therefore believes it is appropriate to extend the moratorium on Food and Drug Administration regulatory efforts to remove saccharin from the market. This will allow time for completion and review of a solid foundation of research on the safety of saccharin.

Furthermore, time will be provided for Congress to consider needed revisions to the food safety laws. The Committee began a reexamination of the existing food safety statutes during the 97th Congress and therefore honored the commitment it made in the 96th Congress report. The conclusions drawn in that committee report continue to be valid and are deserving of repetition as this committee's continuing views. The Congress should not be asked to intervene in the regulatory process and overrule existing statutes on a product-by-product basis as is currently the case. The committee believes that if current regulatory statutes do not permit these issues to be fairly resolved, then those statutes should be reexamined.

The National Academy of Sciences has recently reviewed our food safety laws and concluded that, ". . . although complex in itself, the law is inadequate to meet changing and increasing problems of food safety."

The committee believes that this conclusion, in light of the growing number of controversies about individual products, argues for a thorough and complete congressional reexamination of the food safety laws. The extension of the moratorium will give the committee the time to complete such an examination. Saccharin can then be considered within the framework of a working law, rather than on a product-by-product basis, as is now the case.

The committee does not intend its action in extending the saccharin moratorium to be interpreted as an endorsement of the view that studies to date have proven saccharin is safe for human consumption; nor should it be inferred that the committee has concluded that saccharin is not safe. But while further, necessary studies are underway, the committee recognizes that many people, including diabetics and others on specific diets, want a no-calorie or low-calorie substitute for sugar and that at the present time saccharin is the only noncaloric substance available. The committee also hopes that industry will make a determined effort to develop a safe alternative to saccharin.

The committee felt strongly that, during the original 18-month moratorium, consumers should be afforded a reasonable opportunity to know which products contain saccharin so that they could make personal judgments concerning its use.

The Saccharin Study and Labeling Act, therefore, authorized the Secretary to place warning labels on products containing saccharin

and required retail establishments that sell saccharin or food containing saccharin to prominently display a notice of the risks to health that may be related to the use of saccharin. This requirement is unchanged and reflects the committee's continued support of consumer choice in this matter. Furthermore, should information become available demonstrating a public health risk from continued risk of saccharin, under S. 89 the FDA would retain the authority to take regulatory action, as currently provided under the Saccharin Study and Labeling Act.

IV. Votes in Committee

Pursuant to section 133(b) of the Legislative Reorganization Act of 1946, as amended, the following is a tabulation of votes in committee:

The committee voted to favorably report the bill without amendment.

V. Congressional Budget Office Cost Estimate

U.S. Congress,
Congressional Budget Office,
Washington, D.C., March 18, 1983.

Hon. Orrin G. Hatch,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, D.C.

Dear Mr. Chairman: As requested by your staff, the Congressional Budget Office has reviewed S. 89, the Saccharin Study and Labeling Act Amendment of 1983, as introduced and referred to the Senate Committee on Labor and Human Resources on January 26, 1983.

The bill would extend for 2 years after enactment the prohibition on removal of saccharin from the market by the Secretary of Health and Human Services acting under the authority of the Federal Food, Drug, and Cosmetic Act. Based on our review, it is expected that no additional cost to the government would be incurred as a result of enactment of this legislation.

Sincerely,

Alice M. Rivlin, *Director.*

VI. Regulatory Impact Statement

The committee anticipates that there will be little if any additional regulatory impact because of this legislation. The bill merely extends for an additional 24 months the original moratorium as enacted under the Saccharin Study and Labeling Act (SSLA) (Public Law 95–203) and extended to June 30, 1981, by Public Law 96–273, and to August 14, 1983, by Public Law 97–42. There are no new labeling or testing requirements in this bill, only the effective date has been changed. Posters and notices will continue to be distributed by the manufacturers of the products or by their trade associations. There may be some minimal costs to industry for additional posters for display in retail stores, however, this should be incurred only where new stores are opened or existing posters need to be replaced because of damage or other similar reasons.

Manufacturers of products containing saccharin will not incur additional expenses related to labeling changes because the basic labeling requirements—prescribed by the law itself (section 4)—are unchanged and have been implemented during the initial moratorium.

VII. Section-by-Section Analysis

The bill contains only one section which amends section III of the Saccharin Study and Labeling Act (Public Law 95–203 as amended by Public Law 96–273 and Public Law 97–42) to extend the prohibition on actions by the Secretary of Health and Human Services to "twenty-four months after the enactment of the Saccharin Study and Labeling Act Amendment of 1983".

VIII. Changes in Existing Law

In compliance with rule XXVI, paragraph 12, of the Standard Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Section 3 of the Saccharin Study and Labeling Act

Sec. 3. During the period beginning on the date of the enactment of this act and ending twenty-four months after the date of enactment of the Saccharin Study and Labeling Act Amendment of [1981,] *1983*, the Secretary—

(1) may not amend or revoke the interim food additive regulation of the Food and Drug Administration of the Department of Health, Education, and Welfare applicable to saccharin and published on March 15, 1977 (section 180.37 of part 180, subchapter B, chapter 1, title 21, Code of Federal Regulations (42 Fed. Reg. 14638)), or

(2) may, except as provided in section 4 and the amendments made by such section, not take any other action under the Federal Food, Drug, and Cosmetic Act to prohibit or restrict the sale or distribution of saccharin, any food permitted by such interim food additive regulation to contain saccharin, or any drug or cosmetic containing saccharin, solely on the basis of the carcinogenic or other toxic effect of saccharin as determined by any study made available to the Secretary before the date of enactment of this Act which involved human studies or animal testing, or both.

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